STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
DIVISION OF HEALTH ENGINEERING
10 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0010

ANGUS S KING, JR
GOVERNOR

KEVIN W CONCANNON
COMMISSIONER

October 30, 2002

Paul Lohaus, Director
USNRC Office of State and Tribal Programs
One White Flint North
11555 Rockville Pike, 3rd Floor
Rockville, MD 20852

Re: Rulemaking: Changes to Radiation Regulations

Dear Mr. Lohaus:

Enclosed please find the proposed regulations to the State of Maine Rules Relating to Radiation Protection (SMRRRP). There will be a public hearing on these proposed rules on November 21, 2002 from 9:00 am – Noon at the DHS offices at 161 Capital Street, Augusta. The comment period for written comments is by the close of business on December 20, 2002. As a reminder, all comments must be submitted to this office in writing to be valid.

These proposed rules are essentially verbatim to 10 CFR Parts 20 & 35, with minor editorial changes to reflect Maine's policies and procedures. The RATS Id numbers affected are as follows:

2002-1; 2002-2

In addition, during the IMPEP review, it was discovered that NRC might not have reviewed our General License regulations found in Part C.6 of the SMRRRP. The corresponding RATS Id # is 2001-01. Please review them to verify compatibility with 10 CFR 31.

If you have any questions, do not hesitate to contact this office at 207-287-5676. Thank you.

Sincerely,

Shawn W. Seeley

STP-006 Template
RIDS DIST. SP05

STP Rec'd 11/4/02

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
DIVISION OF HEALTH ENGINEERING
10 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0010

ANGUS S. KING, JR
GOVERNOR

KEVIN W CONCANNON
COMMISSIONER

October 17, 2002

To: All Maine Specific License Holders
ACR Members/Consultants/OSTP-NRC

From: Shawn Seeley, Senior Radioactive Materials Inspector
Maine Radiation Control Program

Re: 2002 Rulemaking

Enclosed please find the proposed changes to the State of Maine Rules Relating to Radiation Protection (Parts A, C, D, ~~& G~~). There will be a public hearing on these proposed rules on November 21, 2002 from 9:00 am – Noon at the DHS offices at 161 Capital Street, Augusta. The comment period for written comments is by the close of business on December 20, 2002. As a reminder, all comments must be submitted to this office in writing to be valid. If you have any questions, do not hesitate to contact this office at 207-287-5676. Thank you.

PART A

GENERAL PROVISIONS

1. **Scope.** Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation; provided, however that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission [1/]

2. **Definitions.**

A. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

(1) "**Absorbed dose**" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the Gray (Gy) and the rad

(2) "**Accelerator**" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

(3) "**Accelerator-produced material**" means any material made radioactive by a particle accelerator. See Appendix B of Part C.

(4) "**Act**" means 22 MRSA c. 160.

(5) "**Activity**" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(6) "**Adult**" means an individual 18 or more years of age.

(7) "**Agency**" means Department of Human Services.

(8) "**Agreement state**" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended ~~(73 Stat. 689)~~

(9) "**Airborne radioactive material**" means any radioactive material dispersed in the air in the form of particulates, dusts, fumes, mists, vapors, or gases.

(10) "**Airborne radioactivity area**" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part D of these regulations, or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed ,during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(11) "**Air-purifying respirator**" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(12) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

1/ Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

(100) "**Principal activities**", as used in this part, means activities authorized by the license, which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(101) "**Production facility**" means production facility as defined in the regulations contained in Part C of these regulations.

(102) "**Public dose**" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Part G , or dose from voluntary participation in medical research programs

(103) "**Pyrophoric liquid**" means any liquid that ignites spontaneously in dry or moist air at or below 130 °F (54.4 °C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

(104) "**Qualified Expert**" means an individual who is either a Radiological Physicist, or an X-ray Survey Technician (see Part F.4.) and has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and advise regarding radiation protection needs. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy.

(105) "**Qualitative fit test (QLFT)**" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(106) "**Quality factor**" (Q) means the modifying factor, listed in Tables I and II of A.13 that is used to derive dose equivalent from absorbed dose.

(107) "**Quantitative fit test (QNFT)**" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(108) "**Rad**" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

(109) "**Radiation**" means ionizing radiation, which includes any or all of the following: gamma and x-rays, alpha and beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles.

(110) "**Radiation Area**" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv), in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(111) "**Radiation dose**" [See "Dose"].

(112) "**Radiation machine**" means any device capable of producing radiation except those, which produce radiation only from radioactive material.

(113) "**Radiation safety officer**" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

(114) "**Radioactive material**" means any solid, liquid, or gas, which emits radiation spontaneously.

(115) "**Radioactivity**" means the transformation of unstable atomic nuclei by the emission of radiation.

(116) "**Radiobioassay**" [See "Bioassay"].

(117) "**Radiological Physicist**" means an individual who.

(a) is certified by the American Board of Radiology in therapeutic radiological physics, diagnostic radiological physics, or medical nuclear physics; or

(b) has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or sealed source teletherapy unit, or

(c) has a Master's degree or Doctorate in physics, biophysics, radiological physics, health physics, or engineering, has had 1 year's full-time training in therapeutic radiological physics; and has had 1 year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

(118) "**Registrant**" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.

(119) "**Registration**" means registration with the Agency in accordance with the regulations adopted by the Agency.

(120) "**Regulations of the U.S. Department of Transportation**" means the regulations in 49 CFR Parts 100-189.

(121) "**REM**" means a special unit of dose equivalent. One millirem (mrem) = 0.001 rem. For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

(a) An exposure of 1 roentgen of x or gamma radiation.

(b) An absorbed dose of 1 rad due to x, gamma, or beta radiation.

(c) An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

(d) An absorbed dose of 0.1 rad due to neutrons or high energy protons; or 2.5×10^7 neutrons/square centimeter incident upon the body; or estimating the energy distribution of the neutron flux with reasonable accuracy as indicated in table 2 of A 13.A(5).

(122) "**Research and development**" means (a) theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(123) "**Residual radioactivity**" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes all radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part D.

(124) "**Restricted area**" means any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

(125) "**Roentgen**" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air. (See "Exposure").

(126) "**Sealed source**" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

(127) "**Self-contained breathing apparatus (SCBA)**" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(128) "**Shallow dose equivalent**" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0 007 centimeter (7 mg/cm^2) ~~averaged over an area of 1 square centimeter~~.

(d) Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

(e) Shall not export such depleted uranium except in accordance with the license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.5.E(1). is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

6. General Licenses - Radioactive Material Other Than Source Material.

A. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of A.4 through A.9, C.3.A(2), C.14, C.21, C.22, and Parts D, J and L of these regulations.

(1) Static Elimination Device. Devices designed for use as static eliminators, which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device

B. Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provision of C.6.B(2), (3), (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.6.B(1) applies only to radioactive material contained in devices, which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.11.D or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21.

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6 B(1) shall file Agency Form HHE 861 "Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices", ~~or~~ Agency Form HHE 862 "Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices" or Agency Form HHE 864 "Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License" with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of these regulations for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

1. Purpose.

A. Part D establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These regulations are issued pursuant to the 22 MRSA, the Radiation Control Act.

B. The requirements of Part D are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

2. Scope. Except as specifically provided in other Parts of these regulations, Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy~~,~~, to exposure from individuals administered radioactive material and released in accordance with Part G, or to voluntary participation in medical research programs.

3. Definitions.

A. As used in Part D:

(1)"**Annual limit on intake**" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

(2)"**Class**" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

(3) "**Declared pregnant woman**" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant..

(4) "**Derived air concentration**" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

D. To implement the ALARA requirements of D.5. B and notwithstanding the requirements in D.14, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR Part 50.34a of the USNRC regulations, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in D.53 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

6. Occupational Dose Limits for Adults.

A. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.11, to the following dose limits:

(1) An annual limit, which is the more limiting of.

(a) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(b) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem)

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(a) A lens dose equivalent of 0.15 Sv (15 rem), and

(b) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.11.E(1) and (2).

C. The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(1) The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

(2) (*Reserved.*)

D. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.46.

E. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

F. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See D.10.E

G. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to D.6.A but shall be included in evaluations required by D.11.D and E.

12. Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.6.

13. Dose to an Embryo/Fetus.

A. The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See D.46 for record keeping requirements.

B. The licensee or registrant shall make efforts to avoid substantial variation[2]/ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.13.A.

C. The dose equivalent to an embryo/fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares her pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with paragraph A of this section if the additional dose equivalent does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

14. Dose Limits for Individual Members of the Public.

A. Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with ~~G.27~~Part G, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.35,[3]/ and

[2]/ The National Council on Radiation Protection and Measurements recommended in NCRP Report No 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

[3]/ Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Part G, does not exceed 0.02 mSv (0.002 rem) in any one hour.

B. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

C. Notwithstanding paragraph A(1) of this section, a licensee may permit visitors to an individual who can not be released in accordance with Part G, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(1) The radiatio dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in Part G, has determined before the visit that it is appropriate.

~~C~~D. A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in D.14.A.; and

(2) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose ALARA.

~~D~~E. In addition to the requirements of Part D, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards

~~E~~F. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

15. Compliance with Dose Limits for Individual Members of the Public.

A. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in D.14.

B A licensee or registrant shall show compliance with the annual dose limit in D.14 by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

(a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(b) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.05 rem (0.5 mSv) in a year.

C. Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

PART G

MEDICAL USE OF RADIOACTIVE MATERIAL

SUBPART A – GENERAL INFORMATION

1. Purpose And Scope.

This part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

2. Definitions. As used in this part, the following definitions apply:

Address of use means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Agreement state means any State with which the U.S. Nuclear Regulatory Commission (NRC) or the U.S. Atomic Energy Commission has entered into effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

Authorized medical or teletherapy physicist means an individual who:

1. Meets the requirements in G.19.A and G.22; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical use license issued by the Agency, NRC, Agreement State, or Licensing State;

b. A permit issued by an Agency, NRC, Agreement State, or Licensing State broad scope medical use licensee.

Authorized nuclear pharmacist means a pharmacist who:

1. Meets the requirements in G.20.A and G.22; or

2. Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by the Agency, NRC, Agreement State, or Licensing State that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an Agency, NRC, Agreement State, or Licensing State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy.

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with Part C.11.I(2)(d).

Authorized user means a physician, dentist, or podiatrist who·

1. Meets the requirements in G 22 and G.190, G.290, G.390, G 392 A , G 394.A, G 490, G 590, G 690 or G.790, or

2 Is identified as an authorized user on:

a An Agency, NRC, Agreement State, or Licensing State license that authorizes the medical use of radioactive material,

b. A permit issued by an Agency, NRC, Agreement State, or Licensing State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

Black Box means the radiopharmaceutical production purification system used in a Cyclotron / PET facility

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters .

Client's address means the area of use or a temporary job site for the purpose of providing mobile nuclear medicine services in accordance with G.31.

Cyclotron means a type of particle accelerator that is used for the production of radioactive material.

Cyclotron/PET facility means a facility comprised of a cyclotron and a nuclear pharmacy that specializes in the preparation of Positron Emission Tomography (PET) radiopharmaceuticals.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual duly registered and licensed to practice dentistry or dental surgery or any branch thereof under 32 MRSA §1082.

High dose-rate remote afterloader as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume

Medical event means an event that meets the criteria in G 3001.

Medical institution means an organization in which more than one medical disciplines is practiced

Medical use means the intentional internal or external administration of radioactive material, or the radiation there from, to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile nuclear medicine service means the transportation of radioactive material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual duly registered and licensed to practice medicine or surgery or any branch thereof under 32 MRSA §3270.

Podiatrist means an individual duly registered and licensed to practice podiatry or any branch thereof under 32 MRSA §3552.

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of unsealed radioactive material as documented:

1. In a written directive; or

2. In accordance with the directions of the authorized user for procedures performed pursuant to G.100 and G.200.

Prescribed dose means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, the total dose and dose per fraction as documented in the written directive;

3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

2. Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

1 Meets the requirements in G.18.A and G.22; or

2 Is identified as a Radiation Safety Officer on a specific medical use license issued by the Agency, NRC, Agreement State, or Licensing State.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training

Teletherapy as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Therapeutic dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive

Type of use means use of radioactive material under G.100, G 200, G.300, G 400, G.500, G 600, G.700 or G.1000.

Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in G 15.

3. Maintenance Of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures The licensee shall maintain adequate safeguards against tampering with and loss of records.

4. Provisions For The Protection Of Human Research Subjects.

A. A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

B If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

1. Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

2. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

C. If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research.

1. Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

2. Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

D. Nothing in this section relieves licensees from complying with the other requirements in this part.

5. License Required.

A. A person may manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued pursuant to these regulations.

B. A specific license is not needed for an individual who:

1. Receives, possesses, uses, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in G.14, unless prohibited by license condition or2. Prepares unsealed radioactive material for medical use in accordance with these regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.14, unless prohibited by license condition.

6. Application For License, Amendment, Or Renewal.

A. An application must be signed by the applicant's or licensee's management.

B. An application for a license for medical use of radioactive material as described in G.100, G.200, G.300, G.400, G.500, G.600, G.700 and G.1000 must be made by:

1. Filing the appropriate HHE Form 850, "Application for Radioactive Material License" that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

2. Submitting procedures required by G.603, G.609, G.610 and G.611, as applicable.

C. A request for a license amendment must be made by:

1. Submitting either the appropriate HHE Form 850, "Application for a Radioactive Material License" or a letter requesting the amendment; and

2. Submitting procedures required by G.603, G.609, G.610, and G.611, as applicable.

D. A request for a license renewal must be made by:

1. Submitting the appropriate HHE Form 850, "Application for a Radioactive Material License"; and

2. Submitting procedures required by G.603, G.609, G.610 and G.611, as applicable.

E. In addition to the requirements in G.6.A, G.6.B and G 6.C, an application for a license or amendment for medical use of radioactive material as described in G.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of Part G.

1. The applicant shall also provide specific information on:

a Radiation safety precautions and instructions,

b. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

c Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

2 The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

F. An applicant that satisfies the requirements specified in Part C 10.B may apply for a Type A specific license of broad scope

7. License Amendments. A licensee shall apply for and must receive a license amendment:

A Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part, but is not authorized on the licensee's current license under this part;

B. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except;

1. For an authorized user, an individual who meets the requirements in G.190.A, G 290.A, G 390 A, G.392.A, G.394.A, G.490 A, G.590.A, G.690.A, and G.22,

2. For an authorized nuclear pharmacist, an individual who meets the requirements in G 20.A and G.22;

3 For an authorized medical physicist, an individual who meets the requirements in G 19.A and G 22;

4. An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

a. On an Agency, NRC, Agreement State, or Licensing State license or other equivalent permit or license recognized by the Agency that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

b. On a permit issued by an Agency, NRC, Agreement State, or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

c. On a permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, or

d. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

C. Before it changes Radiation Safety Officers, except as provided in G.12.C;

D. Before it receives radioactive material in excess of the amount, or in a different form, or receives a different radionuclide than is authorized on the license;

E. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either G.100 or G.200,

F. Before it changes the address(es) of use identified in the application or on the license, and

G. Before it revises procedures required by G.603, G.609, G.610, and G.611, as applicable, where such revision reduces radiation safety.

8. Notifications.

A A licensee shall provide the Agency a copy of the board certification and the Agency, NRC, Agreement State, or Licensing State license for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under G.7.B.1 through G.7.B 4.

B. A licensee shall notify the Agency by letter no later than 30 days after:

1. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist , permanently discontinues performance of duties under the license or has a name change;

2. The licensee's mailing address changes;

3. The licensee's name changes, but the name change does not constitute a transfer of control of the license;

4. The licensee has added to or changed the areas of use as identified in the application or on the license.

C. The licensee shall mail the documents required in this section to: Radiation Control Program, 11 State House Station, Augusta, ME, 04333-0011.

9. Exemptions Regarding Type A Specific Licenses Of Broad Scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from --

A. The provisions of G.6.C regarding the need to file an amendment to the license for medical use of radioactive material, as described in G.1000;

B. The provisions of G.7.B;

C. The provisions of G.7.E regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

D. The provisions of G.8.A;

1. The provisions of G.8.B.1 for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

2. The provisions of G.8.B.4 regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with G.100 or G.200;

E. The provisions of G.17.A.

10. License Issuance.

A. The Agency shall issue a license for the medical use of radioactive material if:

1. The applicant has filed HHE Form 850 "Application for a Radioactive Material License" in accordance with the instructions in G.6;

2. The applicant has paid any applicable fee as provided in Part C;

3. The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety; and

4. The applicant meets the requirements of Part C

B. The Agency shall issue a license for mobile nuclear medicine service if the applicant:

1. Meets the requirements in G.10.A; and

2. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with G.30.

11. Specific Exemptions.

The Agency may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest

~~6. ALARA Program.~~

~~A. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with D.1.B. of these regulations.~~

~~B. To satisfy the requirement of G.6.A.:~~

~~(1) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or~~

~~(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.~~

~~C. The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.~~

~~D. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:~~

~~(1) A commitment by management to keep occupational doses as low as reasonably achievable;~~

~~(2) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;~~

~~(3) Personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and~~

~~(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.~~

~~7. Radiation Safety Officer.~~

~~A. A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.~~

~~B. The Radiation Safety Officer shall:~~

~~(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;~~

~~(2) Implement written policy and procedures for:~~

~~(a) Authorizing the purchase of radioactive material;~~

~~(b) Receiving and opening packages of radioactive material;~~

~~(c) Storing radioactive material;~~

~~(d) Keeping an inventory record of radioactive material;~~

~~(e) Using radioactive material safely;~~

~~(f) Taking emergency action if control of radioactive material is lost;~~

~~(g) Performing periodic radiation surveys;~~

~~(h) Performing checks of survey instruments and other safety equipment;~~

~~(i) Disposing of radioactive material;~~

~~(j) Training personnel who work in or frequent areas where radioactive material is used or stored; and~~

~~(k) Keeping a copy of all records and reports required by the Agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and~~

~~(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; or~~

~~(4) For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.~~

8. **Radiation Safety Committee.** Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

A. The Committee shall meet the following administrative requirements:

(1) Membership must consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee shall meet at least once each calendar quarter.

(3) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting shall include:

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots, and

(f) Document any reviews required in G-6.C and G-8.B.(

5) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.

B. To oversee the use of licensed material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

9. **Quality Management Program.**

A. Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive[11] is prepared for:

(a) Any teletherapy radiation dose;

(b) Any gamma stereotactic radiosurgery radiation dose;

(c) Any brachytherapy radiation dose;

(d) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131;

(e) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131, or

---

[11] If because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

~~(f) Any PET radiation dose.~~
~~(2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;~~
~~(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;~~
~~(4) That each administration is in accordance with the written directive; and~~
~~(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.~~
~~B. The licensee shall:~~
~~(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:~~
~~(a) A representative sample of patient administrations,~~
~~(b) All recordable events, and~~
~~(c) All misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;~~
~~(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph A of the section; and~~
~~(3) Retain records of each review, including the evaluations and finding of the review, in an auditable form for three years.~~
~~C. The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:~~
~~(1) Assembling the relevant facts including the cause;~~
~~(2) Identifying what, if any, corrective action is required to prevent recurrence; and~~
~~(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.~~
~~D. The licensee shall retain:~~
~~(1) Each written directive; and~~
~~(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph A(1) above, in an auditable form, for three years after the date of administration.~~
~~E. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the agency within 30 days after the modification has been made.~~
~~F. Reporting Requirements:~~
~~(1) Each applicant for a new license, as applicable, shall submit to the agency in accordance with section 11 of part A, a quality management program as part of the application for a license and implement the program upon issuance of the license by the agency.~~
~~(2) Each existing licensee, as applicable, shall submit to the agency in accordance with section 11 of part A, by January 27, 1995 a written certification that the quality management program has been implemented along with a copy of the program.~~
~~**10. Statement of Authorities and Responsibilities.**~~
~~A. A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:~~
~~(1) Identify radiation safety problems;~~
~~(2) Initiate, recommend, or provide solutions; and~~
~~(3) Verify implementation of corrective actions.~~
~~B. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.~~

12. Authority And Responsibilities For The Radiation Protection Program

A. In addition to the radiation protection program requirements of- Part D a licensee's management shall approve in writing:

1. Requests for a license application, renewal, or amendment before submittal to the Agency;

2 Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

3. Radiation protection program changes that do not require a license amendment and are permitted under G.13;

B. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee- approved procedures and regulatory requirements.

C. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under G 18 and G.22, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in G 12 G-, if the licensee takes the actions required in- G 12 B, G 12.E, G 12 G and G 12 H and notifies the Agency in accordance with G 18.B.

D A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with G.12 C, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license

E. A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

F. Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, and H of Part G, or two or more types of units under Subpart H of Part G, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate

G. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1 Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3 Stop unsafe operations; and,

4. Verify implementation of corrective actions.

H. A licensee shall retain a record of actions taken under G 12.A, G 12.B, and G.12 E in accordance with G.2012.

13. Radiation Protection Program Changes.

A. A licensee may revise its radiation protection program without Agency approval if:

1. The revision does not require a license amendment under G 7,

2 The revision is in compliance with the regulations and the license;

3 The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

4. The affected individuals are instructed on the revised program before the changes are implemented.

B. A licensee shall retain a record of each change in accordance with G 2013

1411. Supervision.

A. A licensee that ~~who~~ permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by G 5 B 1~~G 3~~ shall:

~~(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;~~

~~(2) Annually review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;~~

~~(3) Require the authorized user to be immediately available to communicate with the supervised individual;~~

~~(4) Require the authorized user to be able to be physically present and available to the supervised individual on 2 hours notice or 3 hours notice for mobile nuclear medicine services;[2/] and~~

~~(5) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients.~~

1. In addition to the requirements in Part D, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

~~B. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under G.3 to:~~

~~(1) Follow the instructions of the supervising authorized user;~~

~~(2) Follow the procedures established by the Radiation Safety Officer; and~~

~~(3) Comply with these regulations and the license conditions with respect to the use of radioactive material.G 12~~

B. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G 5.B.2, shall:

1. In addition to the requirements in Part D, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, these regulations, and license conditions.

C. A licensee that permits supervised activities under G.14 A and G.14.B is responsible for the acts and omissions of the supervised individual.

~~**12. Visiting Authorized User.**~~

~~A. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:~~

~~(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;~~

~~(2) The licensee has a copy of an Agency, Agreement State, Licensing State or U S. Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; and~~

~~(3) Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, Licensing State or U S Nuclear Regulatory Commission license are performed by that individual.~~

~~B. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in G.12 A.~~

2/ The supervising authorized user need not be present for each use of radioactive material.

~~C. A licensee shall retain copies of the records specified in G 12 A for 5 years from the date of the last visit~~

15. Written Directives.

A. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1 11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed radioactive- material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable The information contained in the oral directive must be documented as soon as possible in writing in the patient's record A written directive must be prepared within 48 hours of the oral directive.

B. The written directive must contain the patient or human research subject's name and the following information:

1. For any administration of quantities greater than 1 11 MBq (30 μCi) of sodium iodide I-131 the dosage,

2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration,

3 For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4 For teletherapy the total dose, dose per fraction, number of fractions, and treatment site;

5 For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

6. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders

a. Before implantation: treatment site, the radionuclide, and dose; and

b. After implantation but before completion of the procedure the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

C A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose

1. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

D. The licensee shall retain a copy of the written directive in accordance with G 2015.

16. Procedures For Administrations Requiring A Written Directive.

A. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1 The patient's or human research subject's identity is verified before each administration, and

2 Each administration is in accordance with the written directive.

B. At a minimum, the procedures required by G.16.A must- address the following items that are applicable to the licensee's use of radioactive material:

1 Verifying the identity of the patient or human research subject,
2 Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

3 Checking both manual and computer-generated dose calculations; and

4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600

C. A licensee shall retain a copy of the procedures required under G.16 A in accordance with G.2016.

~~13. Mobile Nuclear Medicine Service Administrative Requirements~~
~~A. The Agency will license mobile nuclear medicine services only in accordance with this part and other applicable requirements of these regulations.~~
~~B. Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes radioactive material at the client's address of use. The mobile nuclear medicine service shall retain the letter for three years after the last provision of service.~~
~~C. A mobile nuclear medicine service shall have all radioactive material delivered directly from the manufacturer or the distributor to the mobile nuclear medicine facility. At no time may the client take receipt of any radioactive material intended for the mobile nuclear medicine service's use.~~
~~14. Notifications, reports, and records of misadministrations.~~
~~A. For a misadministration:~~
~~(1) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of the misadministration.~~
~~(2) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; a brief description of the event; why the event occurred, the effect on the patient; what improvements are needed to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.G.14.A(3)~~
~~(3) The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.~~
~~(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:~~
~~(a) A copy of the report that was submitted to the NRC; or~~
~~(b) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.~~
~~B. Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.~~
~~C. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.~~

17~~15~~. **Suppliers For Radioactive Material, Sealed Sources Or Devices For Medical Use.**

For medical use, a licensee may only use ~~A licensee shall use for medical use only~~:

A Radioactive material, sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of the NRC, Agreement State or Licensing State.~~another Agreement State, a Licensing State or the U S Nuclear Regulatory Commission; and~~

B. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U S Department of Health and Human Services, Food and Drug Administration

C Sealed sources or devices noncommercially transferred from a Part G licensee, or

D~~C~~ Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of the NRC, Agreement State, or Licensing State ~~another Agreement State, a Licensing State, or the U S Nuclear Regulatory Commission~~

18. Training For Radiation Safety Officer.

Except as provided in G 21, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G 12 to be an individual who:

A. Is certified by a specialty board whose certification process includes all of the requirements in G.18 B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Health Physics in Comprehensive Health Physics; or

2 American Board of Radiology; or,

3. American Board of Nuclear Medicine, or,

4 American Board of Science in Nuclear Medicine, or

5. Board of Pharmaceutical Specialties in Nuclear Pharmacy, or

6. American Board of Medical Physics in radiation oncology physics; or

7 Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

8 American Osteopathic Board of Radiology; or

9. American Osteopathic Board of Nuclear Medicine; or

B. 1 Has completed a structured educational program consisting of both

a 200 hours of didactic training in the following areas:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, NRC, Agreement State or Licensing State license that authorizes similar type(s) of use(s) of radioactive material involving the following.

(1) Shipping, receiving, and performing related radiation surveys

(2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(3) Securing and controlling radioactive material;

(4) Using administrative controls to avoid mistakes in the administration of radioactive material;

(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(6) Using emergency procedures to control radioactive material; and

(7) Disposing of radioactive material; and

2 Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in G.18.B and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

C. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

19. Training For An Authorized Medical Physicist.

Except as provided in G.21, the licensee shall require the authorized medical physicist to be an individual who:

A Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.19 B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Radiology in Therapeutic radiological physics; or

2. American Board of Radiology in Roentgen ray and gamma ray physics; or

3. American Board of Radiology in X-ray and radium physics; or

4. American Board of Radiology in Radiological physics; or

5. American Board of Medical Physics in radiation oncology physics; or

B. 1 Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in G.27, G.406, G.606, G 607, G.608, G 609, G.610, G 611 and G.613, as applicable; and

2. Has obtained written certification that the individual has satisfactorily completed the requirements in G.19.B 1 and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in G.19 or equivalent NRC, Agreement State, or Licensing State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

20. Training For An Authorized Nuclear Pharmacist.

Except as provided in G.21, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

A. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in G.20 B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State,

1. Board of Pharmaceutical Specialties in nuclear pharmacy; or

B. 1. Has completed 700 hours in a structured educational program consisting of both

a Didactic training in the following areas:

i. Radiation physics and instrumentation,

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity,

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology and

b. Supervised practical experience in a nuclear pharmacy involving:

(1) Shipping, receiving, and performing related radiation surveys,

(2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides,

(3) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(4) Using administrative controls to avoid medical events in the administration of radioactive material; and

(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G 20.B 1 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

21. Training For Experienced Radiation Safety Officer, Teletherapy Or Medical Physicist, Authorized User, And Nuclear Pharmacist.

A. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on an Agency, NRC, Agreement State, or Licensing State license before *[insert date 6 months from publication of the Final Rule]* need not comply with the training requirements of G 18, G 19, or G 20, respectively.

B. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, NRC, Agreement State, or Licensing State, before *[insert date 6 months from publication of the Final Rule]* who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of Part G.

22. Recentness Of Training.

The training and experience specified in Subparts B, D, E, F, G, H, I and J of Part G must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed

~~16. Quality Control of Imaging Equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.~~

~~17. Possession, Use, Calibration, and Check of Dose Calibrators.~~

~~A. A licensee shall possess and use a dose calibrator to measure the activity of dosages of radionuclides prior to administration to each patient or human research subject.~~

~~B. A licensee shall:~~

~~(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;~~

~~(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;~~

~~(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered; and~~

~~(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.~~

~~C. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.~~

~~D. A licensee shall also perform checks and tests required by G.17.B. following adjustment or repair of the dose calibrator.~~

~~E. A licensee shall retain a record of each check and test required by G.17 for 2 years. The records required by G.17.B shall include:~~

~~(1) For G.17.B (1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;~~

~~(2) For G.17.B (2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the Radiation Safety Officer;~~

~~(3) For G.17.B (3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and~~

~~(4) For G.17.B.(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.~~

23. Possession, Use, And Calibration Of Instruments Used To Measure The Activity Of Unsealed Radioactive Material.

A. For direct measurements performed in accordance with G.25, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. A licensee shall calibrate the instrumentation required in G.23.A in accordance with nationally recognized standards or the manufacturer's instructions.

C. A licensee shall retain a record of each instrument calibration required by this section in accordance with G.2023.

2418. Calibration ~~And Check~~ Of Survey Instruments.

A A licensee shall calibrate ~~ensure that~~ the survey instruments used to show compliance with this part and Part D ~~have been calibrated~~ before first use, annually, and following a repair that affects the calibration. A licensee shall:

~~B. To satisfy the requirements of G.18.A., the licensee shall:~~

1.~~(1)~~ Calibrate all ~~required~~ scales with readings up to 10 mSv ~~1000 millirems~~ (1000 mrem~~10 mSv~~) per hour with a radiation source,

2.~~(2)~~ Calibrate two separated readings on ~~For~~ each scale or decade that will be used to show compliance ~~shall be calibrated, calibrate two separate readings~~; and

3.~~(3)~~ Conspicuously note on the instrument ~~the apparent dose rate from a dedicated check source as determined at the time of calibration, and~~ the date of calibration.

~~C. To satisfy the requirements of G.18.B., the licensee shall:~~
~~(1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and~~
~~(2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.~~

B~~D~~. A licensee may not use ~~shall check each~~ survey instruments if the difference between the indicated exposure rate and the calibrated exposure rater is more than 20 percent ~~for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.~~

C~~E~~. The licensee shall retain a record of each survey instrument calibration in accordance with G.2024~~required in G.18.A. for 2 years. The record shall include:~~

~~(1) A description of the calibration procedure; and~~
~~(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.~~
~~F. To meet the requirements of G.18.A., .B., and C., the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.18.E. shall be maintained by the licensee.~~
~~**19. Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.**~~
~~A. This section does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to Parts C and G, or equivalent US Nuclear Regulatory Commission, Agreement State, or Licensing State requirements.~~
~~B. For other than unit dosages obtained pursuant to paragraph A of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:~~
~~(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; AND~~
~~(2) Check each instrument for constancy and proper operation at the beginning of each day of use.~~
~~20. Assay of Radiopharmaceutical Dosages. A licensee shall:~~

~~A. Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 microcuries (370 kBq) of a photon-emitting radionuclide;~~

~~B. Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries (370 kBq); and~~

~~C. Retain a record of the assays required by G.20.A. and B. for 2 years. To satisfy this requirement, the record shall contain the:~~

~~(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;~~

~~(2) Patient's name, and identification number if one has been assigned;~~

~~(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 microcuries (370 kBq);~~

~~(4) Date and time of the assay and administration; and~~

~~(5) Initials of the individual who performed the assay.~~

25. Determination Of Dosages Of Unsealed Radioactive Material For Medical Use.

A. A licensee shall determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination must be made by:

1. Direct measurement of radioactivity; or

2. A decay correction, based on the activity or activity concentration determined by:

a. A manufacturer or preparer licensed under Part C or equivalent NRC, Agreement State, or Licensing State requirements; or

b. An Agency, NRC, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

C. For other than unit dosages, this determination must be made by:

1. Direct measurement of radioactivity;

2. Combination of measurement of radioactivity and mathematical calculations; or

3. Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Part C. or equivalent NRC, Agreement State, or Licensing State requirements.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E A licensee shall retain a record of the dosage determination required by this section in accordance with G.2025.

26~~21~~. Authorization For Calibration, Transmission, And Reference Sources.

Any person authorized by G.~~53~~ for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

A. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by persons ~~specifically~~ licensed pursuant to Part C of these regulations or equivalent ~~provisions of the~~ NRC, Agreement State, or Licensing State ~~U.S. Nuclear Regulatory Commission, Agreement State or Licensing State~~ regulations.~~and that do not exceed 15 millicuries (555 MBq) each;~~

B. Sealed sources, not exceeding 1.11 GBq (30mCi) each, redistributed by a person licensed under Part C.11.K providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions ~~Any radioactive material listed in G-100 or G-200 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);~~

C. Any radioactive material ~~listed in G-100 or G.200~~ with a half- life not longer ~~greater~~ than 120 ~~100~~ days in individual amounts not to exceed 0 56 GBq (15 mCi).~~200 microcuries (7 4 MBq) each; and~~

D Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller 7 4 MBq (200 µCi) or 1000 times the quantities in Appendix C of Part D of these regulations.

E~~D~~. Technetium-99m in ~~individual~~ amounts as needed.~~not to exceed 50 millicuries (1 85 GBq)~~

2722. Requirements For Possession Of Sealed Sources And Brachytherapy Sources.

A. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer ~~or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users~~

B. A licensee in possession of a sealed source shall ~~assure that:~~

(1.) Test t~~T~~he source ~~is tested~~ for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2.) Test t~~T~~he source ~~is tested~~ for leakage at intervals not to exceed 6 months or at other intervals approved by the Agency, NRC, Agreement State, or Licensing State~~Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission~~ in the Sealed Source and Device Registry

C. To satisfy the leak test requirements of G 27 B ~~G 22 B~~. the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0 005 µCi) of radioactive material in the sample ~~assure that:~~

~~(1) Leak tests are capable of detecting the presence of 0 005 microcurie (185 Bq) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0 001 microcurie (37 Bq) per 24 hours,~~
~~(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and~~
~~(3) Test samples are taken when the source is in the "off" position~~

D. A licensee shall retain leak test records in accordance with G.2027 A ~~for 5 years~~. ~~The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer~~

E. If the leak test reveals the presence of 185 Bq (0.005 µCi) ~~microcurie (185 Bq)~~ or more of removable contamination, the licensee shall ~~:~~

(1.) Immediately withdraw the sealed source from use and store dispose, or cause it to be repaired ~~it~~ in accordance with the requirements of these regulations; and

(2.) File a report with the Agency within 5 days of ~~receiving~~ the leak test in accordance with G.3003 ~~results with the Agency describing the equipment involved, the test results, and the action taken~~

F. A licensee need not perform a leak test on the following sources:

(1.) Sources containing only radioactive material with a half-life of less than 30 days,

(2.) Sources containing only radioactive material as a gas;

(3.) Sources containing 3.7 MBq (100 µCi) ~~microcuries (3.7 MBq)~~ or less of beta or gamma~~photon~~-emitting material or 0.37 MBq (10 µCi) ~~microcuries (370 kBq)~~ or less of alpha-emitting material;

(4.) Seeds of iridium-192 encased in nylon ribbon; and

(5.) Sources stored and not being used. However, t~~T~~he licensee shall~~, however,~~ test each such source for leakage before any use or transfer unless it has been leak tested ~~for leakage~~ within 6 months before the date of use or transfer.

G. A licensee in possession of a sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. ~~at intervals not to exceed 3 months.~~ The licensee shall retain each inventory record in accordance with G.2027.B. ~~for 5 years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.~~

~~H. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.~~

~~I. A licensee shall retain a record of each survey required in G.22.H for 2 years. The record shall include the date of the survey, a sketch of each area that was surveyed, and the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.~~

28. **Labeling Of Vials And Syringes**

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

~~**23. Syringe Shields.**~~

~~A. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.~~

~~B. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient.~~

~~**24. Syringe Labels.** A licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of clinical procedure to be performed, or the patient's name.~~

~~**25. Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.~~

~~**26. Vial Shield Labels.** A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.~~

29~~27~~. **Surveys For ~~Contamination And~~ Ambient Radiation Dose Rate.**

A. In addition to the surveys required by Part D, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

B. A licensee does not need to perform the surveys required by G 29 A in an area(s) where patients or human research subjects are confined when they cannot be released under G 30.

C. A licensee shall retain a record of each survey in accordance with G.2029.

~~A. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.~~

~~B. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.~~

~~C. A licensee shall conduct the surveys required by G 27 A. and .B so as to able to measure dose rates as low as 0.1 millirem (1.0 (Sv) per hour.~~

~~D. A licensee shall establish dose rate action levels for the surveys required by G.27.A. and B and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.~~

~~E. A licensee shall survey for removable contamination each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.~~

~~F. A licensee shall conduct the surveys required by G.27.E. so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).~~

~~G. A licensee shall establish removable contamination action levels for the surveys required by G.27.E. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.~~

~~H. A licensee shall retain a record of each survey required by G.27.A., B., and E. for 2 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.~~

3028.Release Of Individuals ~~Patients~~ Containing Unsealed Radioactive Material ~~Radiopharmaceuticals~~ Or ~~Permanent~~ Implants Containing Radioactive Material.

A. _ A~~The~~ licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material ~~radiopharmaceuticals~~ or ~~permanent~~ implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) ~~500 millirems (5mSv)~~.

B. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem) ~~100 millirem (1mSv)~~. If the total effective dose equivalent to a nursing ~~breast-feeding~~ infant or child could exceed 1 mSv (0.1 rem) ~~100 millirem (1mSv)~~ assuming there were no interruption of breast-feeding, the instructions must ~~shall~~ also include:

1. Guidance on the interruption or discontinuation of breast-feeding, and

2. Information on the potential consequences, if any, of failure to follow guidance.

C. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2030.A., ~~for 3 years after the date of release, if the total effective dose equivalent is calculated by~~

~~(1)Using the retained activity rather than the activity administered,~~
~~(2)Using an occupancy factor less than 0.25 at 1 meter,~~
~~(3)Using the biological or effective half-life, or~~
~~(4)Considering the shielding by tissue.~~

D. The licensee shall maintain a record~~, for 3 years after the date of release, that~~ of instructions ~~were~~ provided to a breast-feeding female ~~woman~~ in accordance with G.2030.B. ~~if the radiation dose to the infant or child could result in a total effective dose equivalent exceeding 500 millirem (5mSv).~~

3129. Provision Of Mobile Nuclear Medicine Service ~~Technical Requirements.~~

A. A licensee providing mobile nuclear medicine service shall:

U.S. Nuclear Regulatory Commission Regulatory Guide 1556, Vol. 9 (draft) ~~8.39~~, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses ~~Release of Patients Administered Radioactive Materials~~," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem) ~~500 millirem (5millisieverts)~~.

1 Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

2 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

3 Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part D of these regulations.

B. A mobile nuclear medicine service shall have all radioactive material delivered directly from the manufacturer or the distributor to the mobile nuclear medicine facility At no time may the client take receipt of any radioactive material intended for the mobile nuclear medicine service's use.

C. A licensee providing mobile medical services shall retain the letter required in G 31.A.1 and the record of each survey required in G 31.A 4 in accordance with G.2031.A and G.2031.B, respectively.

~~A. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;~~
~~B Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;~~
~~C. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;~~
~~D. Check survey instruments and dose calibrators as required in G 17.B.(1), G.17.D., G.17.E and G.18.D., and check all other transported equipment for proper function before medical use at each location of use;~~
~~E. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and~~
~~F. Retain a record of each survey required by G.29.E for 2 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.~~
~~30. Storage of Volatiles and Gases.~~
~~A. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.~~
~~B. A licensee shall store and use a multidose container in a properly functioning fume hood.~~

3234. Decay-In-Storage.

A. A licensee may hold radioactive material with a physical half-life of less than 120 ~~65~~ days for decay-in-storage before disposal without regard to its radioactivity if it ~~in ordinary trash and is exempt from the requirements of D.33 of these regulations if the licensee:~~

~~(1) Holds radioactive material for decay a minimum of 10 half-lives;~~

~~(2)~~1 Monitors radioactive material at the ~~container~~ surface before disposal ~~as ordinary trash~~ and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding; and

~~(3)~~2. Removes or obliterates all radiation labels; ~~and~~ except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

~~(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.~~

B A ~~For radioactive material disposed in accordance with G-31 A. the~~ licensee shall retain a record for ~~of~~ each disposal permitted under G.32.A in accordance with G.2032. ~~for 2 years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclide disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.~~

SUBPART D – UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED ~~Uptake, Dilution, and Excretion~~

100. Use Of Unsealed Radioactive Material For Uptake, Dilution, And ~~Or~~ Excretion Studies For Which A Written Directive Is Not Required.

Except for quantities that require a written directive under G 15 ~~A. A~~a licensee may use ~~for uptake, dilution, or excretion studies~~ any unsealed radioactive material, ~~for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA),~~ prepared for medical use for uptake, dilution, or excretion studies that is: ~~either:~~

A. ~~1.~~ Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent NRC, Agreement State, or Licensing State~~US Nuclear Regulatory Commission, Agreement State or Licensing State~~ requirements; or

B. ~~2.~~ Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Part G, or an individual under the supervision of either as specified in Part G.14; or

C. Obtained from and prepared by an Agency, NRC, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

D. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA)

~~B. A licensee using a radiopharmaceutical specified in G.100.A. for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.~~

190. Training for uptake, dilution, and excretion studies.

Except as provided in G.21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G 100 to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.190 C and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Nuclear Medicine in nuclear medicine; or,

2. American Board of Radiology in diagnostic radiology; or,

3. American Osteopathic Board of Radiology in diagnostic radiology or radiology; or

4. Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

5 American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

B. Is an authorized user under G.290 or G.390 or equivalent NRC, Agreement State, or Licensing State requirements; or

C. 1. Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include –

a. Classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology; and

b. Work experience, under the supervision of an authorized user who meets the requirements in G 190, G 290, or G 390 or equivalent NRC, Agreement State, or Licensing State requirements, involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys,

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters,

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G 190, G.290 or G.390 or equivalent NRC, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G 190.C 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G 100

~~101. Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 0 (Sv) per hour to 50 millirems (500 (Sv) per hour. The instrument shall be operable and calibrated in accordance with G 18.~~

~~IMAGING AND LOCALIZATION~~

200. Use Of Unsealed Radioactive Material For Imaging And Localization Studies For Which A Written Directive Is Not Required.

~~A.~~ Except for quantities that require a written directive under G.15, aA licensee may use for any unsealed radioactive material ~~imaging and localization studies any unsealed radioactive material~~ prepared for medical use for ~~that is either:~~ imaging and localization studies that is:

A.~~(1)~~. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent NRC, Agreement State, or Licensing State~~US Nuclear Regulatory Commission, Agreement State or Licensing State~~ requirements; or

B.~~(2)~~. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in ~~Part~~ G.290 or G.390, or an individual under the supervision of either as specified in ~~Part~~ G.14;

C. Obtained from and prepared by an Agency, NRC, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

D. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA).

~~(3) This section includes any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).~~

~~B. A licensee using radiopharmaceuticals specified in G.200.A. for clinical procedures shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.~~

~~C. A licensee shall elute generators in compliance with G.201. and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.~~

~~D. Technetium-99m pertechnetate as an aerosol for lung function studies is not subject to the restrictions in G.200 B.:~~

~~E. Provided the conditions of G 202 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.~~

201. Permissible Molybdenum-99 Concentration.

A. A licensee may ~~shall~~ not administer to humans a radiopharmaceutical containing more than 0.15 kilobecquerel ~~microcurie~~ of molybdenum-99 per megabecquerel ~~millicurie~~ of technetium-99m (0.15 microcurie ~~kilobecquerel~~ of molybdenum-99 per millicurie ~~megabecquerel~~ of technetium-99m).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with G.201.A

C If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with G.2201.

~~B. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.~~

~~C. A licensee who must measure molybdenum concentration shall retain a record of each measurement for 3 years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.~~

~~D. A licensee shall report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in G.201.A.~~

290 Training for imaging and localization studies.

Except as provided in G.21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who:

A Is certified by a medical specialty board whose certification process includes all of the requirements in G.290.C and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Nuclear Medicine in nuclear medicine; or,

2. American Board of Radiology in diagnostic radiology; or,

3 American Osteopathic Board of Radiology in diagnostic radiology or radiology; or

4. Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

5. American Osteopathic Board of Nuclear Medicine in nuclear medicine; or.

B Is an authorized user under G 390 or equivalent NRC, Agreement State, or Licensing State requirements; or

C. 1 Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

a Classroom and laboratory training in the following areas

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity,

(4) Chemistry of radioactive material for medical use;

(5) Radiation biology; and

b. Work experience, under the supervision of an authorized user, who meets the requirements in G 290 or G 390 or equivalent NRC, Agreement State, or Licensing State requirements, involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys,

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(6) Administering dosages of radioactive drugs to patients or human research subjects; and

(7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2 Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.290 or G.390 or equivalent NRC, Agreement State or Licensing State requirements, that the individual has satisfactorily completed the requirements in G 290.C.1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G 200.

~~202. Control of Aerosols and Gases.~~

~~A A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by D.6 and D.14 of these regulations.~~

~~B The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.~~

~~C. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.~~

~~D Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit referenced in Part D 6 of these regulations. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.~~

~~E A licensee shall post the time calculated in G.202 D at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.~~

F. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 2 years.

G. A copy of the calculations required in G.202.D shall be recorded and retained for the duration of the license.

203. **Possession of Survey Instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 (Sv) per hour to 50 millirems (500 (Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 (Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with G.18.

SUBPART E – UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE REQUIRED
~~Radiopharmaceuticals for Therapy~~

300. Use of Unsealed Radioactive Material For Which A Written Directive Is Required. ~~Radiopharmaceuticals for Therapy.~~

A. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required ~~therapeutic administration any unsealed radioactive material prepared for medical use~~ that is ~~either:~~

1 ~~(1)~~ Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent NRC, Agreement State, or Licensing State~~US Nuclear Regulatory Commission, Agreement State or Licensing State~~ requirements, or

2 ~~(2)~~. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in ~~Part~~ G 290 or G 390, or an individual under the supervision of either as specified in ~~Part~~ G.14; or

3. Obtained from and prepared by an Agency, NRC, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA); or

4 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA)

~~B. Any unsealed radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.~~

301. Safety Instruction.

In addition to the requirements of Part J.3

A. A licensee shall provide ~~oral and written~~ radiation safety instruction initially and at least annually, to ~~for all~~ personnel caring for patients or human research subjects who cannot be released under G 30 ~~undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed 1 year.~~ To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include

~~B. To satisfy G 301 A, the instruction shall describe the licensee's procedures for~~

1 ~~(1)~~ Patient ort human research subject control;

2. ~~(2)~~ Visitor control, including:

a Routine visitation to hospitalized individuals in accordance with Part D 14.A 1 and

b. Visitation authorized in accordance with Part D.14 C;

3. ~~(3)~~ Contamination control;

4. ~~(4)~~ Waste control; and

5 ~~(5)~~ Notification of the Radiation Safety Officer or his or her designee, and the authorized user if the patient or human research subject has a medical emergency or dies ~~in case of the patient's death or medical emergency~~

BC. A licensee shall retain a record of individuals receiving instruction in accordance with G.2301. ~~keep a record of individuals receiving instruction required by G.301 A., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Agency for 2 years.~~

302. Safety Precautions.

A. For each patient or human research subject who cannot be released under G.30, ~~receiving radiopharmaceutical therapy and hospitalized for compliance with G 28,~~ a licensee shall:

1.~~(1)~~ Quarter the patient or human research subject either in:

a. ~~Provide~~ A ~~a~~ private room with a private sanitary facility, or

b. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under G.30.

2. Visibly p~~P~~ost the patient's or human research subject's room ~~door~~ with a "~~Caution:~~ Radioactive Materials" sign.

3. ~~and~~ N~~n~~ote on the door or i~~o~~n the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

~~(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;~~

~~(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of D.14 of these regulations and retain for 2 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;~~

4.~~(5)~~ Either monitor material and items removed from the patient's or human research subject's room to determine that their radioactivity ~~any contamination~~ cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

~~(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;~~

~~(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and~~

~~(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine 131 within 3 days after administering the dosage, and retain for the period required by D.46. of these regulations a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.~~

B. A licensee shall notify the Radiation Safety Officer or his or her designee, and the authorized user as soon as possible ~~immediately~~ if the patient or human research subject ~~dies or~~ has a medical emergency or dies.

~~303. Possession of Survey Instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 (Sv) per hour to 50 millirems (500 (Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 (Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with G.18.~~

390 Training for use of unsealed radioactive material for which a written directive is required.

Except as provided in G 21, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who

A Is certified by a medical specialty board whose certification process includes all of the requirements in G 390.B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Nuclear Medicine; or

2. American Board of Radiology in radiology, therapeutic radiology, or radiation oncology, or

3. Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

4. American Osteopathic Board of Radiology after 1984, or

B. 1. Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive The training and experience must include:

a. Classroom and laboratory training in the following areas:

(2) Radiation physics and instrumentation;

(3) Radiation protection;

(4) Mathematics pertaining to the use and measurement of radioactivity;

(5) Chemistry of radioactive material for medical use; and

(6) Radiation biology, and

b. Work experience, under the supervision of an authorized user who meets the requirements in G.390 A, G.390 B or equivalent NRC, Agreement State, or Licensing State requirements. A supervising authorized user, who meets the requirements in G 390.B must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve.

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters,

(3) Calculating, measuring, and safely preparing patient or human research subject dosages,

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(6) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(7) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status

(a) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(b) Oral administration of greater than 1 22 Gigabecquerels (33 millicuries) of sodium iodide I-131 ;

---

1 Experience with at least 3 cases in Category (~~VII~~G)(2) also satisfies the requirement in Category (G)(1).

(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(d) Parenteral administration of any other radionuclide; and

2. Has obtained written certification that the individual has satisfactorily completed the requirements in G.390.B.1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G 300 The written certification must be signed by a preceptor authorized user who meets the requirements in G.390.A, G.390.B, or equivalent NRC, Agreement State, or Licensing State requirements. The preceptor authorized user, who meets the requirements in G.390B., must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

392. Training For The Oral Administration Of Sodium Iodide I-131 Requiring A Written Directive In Quantities Less Than Or Equal To 1.22 Gigabecquerels (33 Millicuries).

Except as provided in G.21, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

A Is certified by a medical specialty board whose certification process includes all of the requirements in G.392.C and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State, or

B. Is an authorized user under G.390.A and G.390.B, for uses listed in G.390.B.1.b(7)(a) or (b), G.394 or equivalent NRC, Agreement State, or Licensing State requirements; or

C. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

a. Radiation physics and instrumentation;
b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2 Has work experience, under the supervision of an authorized user who meets the requirements in G.390.A., G.390.B , G.392, G.394 or equivalent NRC, Agreement State, or Licensing State requirements. A supervising authorized user who meets the requirements in G.390.B, must have experience in administering dosages as specified in *G 390.B..1b(7)(a) or (b).* The work experience must involve:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

c Calculating, measuring, and safely preparing patient or human research subject dosages;

d Using administrative controls to prevent a medical event involving the use of radioactive material;

e Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

3 Has obtained written certification that the individual has satisfactorily completed the requirements in G 392 C 1 and G.392.C 2 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300 The written certification must be signed by a preceptor authorized user who meets the requirements in G.390 A, G 390 B, G.392, G.394, or equivalent NRC, Agreement State, or Licensing State requirements A preceptor authorized user, who meets the requirement in G 390 B, must have experience in administering dosages as specified in G.390 B 1 a(7)(a) or (b)

394 Training For The Oral Administration Of Sodium Iodide I-131 Requiring A Written Directive In Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries).

Except as provided in G.21, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1 22 Gigabecquerels (33 millicuries), to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.394.C and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State; or

B. Is an authorized user under G 390 A and G 390 B for uses listed in G.390 B 1 b((7)(b), or equivalent NRC, Agreement State, or Licensing State requirements; or

C. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive The training must include:

a Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d Chemistry of radioactive material for medical use; and

e. Radiation biology, and

2. Has work experience, under the supervision of an authorized user who meets the requirements in G.390.A, G.390 B, G 394, or equivalent NRC, Agreement State, or Licensing State requirements. A supervising authorized user, who meets the requirements in G 390 B must have experience in administering dosages as specified in
G 390 B.1.b(7)(b). The work experience must involve:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d Using administrative controls to prevent a medical event involving the use of radioactive material;

e Using procedures to contain spilled radioactive material safely and using proper decontamination procedures, and

f Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131, and

3. Has obtained written certification that the individual has satisfactorily completed the requirements in G.394.C 1 and G 394.C 2 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written certification must be signed by a preceptor

authorized user who meets the requirements in G.390.A, G.390.B, G.394, or equivalent NRC, Agreement State, or Licensing State requirements. A preceptor authorized user, who meets the requirements in G.390B, must have experience in administering dosages as specified in G.390.B.1.b(7)(b)

SUBPART F – MANUAL ~~SOURCES FOR~~ BRACHYTHERAPY

400. Use of Sources ~~F~~for Manual Brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses~~:~~ ~~the following sources in accordance with the manufacturer's radiation safety and handling instructions:~~

A. As approved in the Sealed Source and Device Registry; or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.17 are met.

~~A. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~
~~B. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~
~~C. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;~~
~~D. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;~~
~~E. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~
~~F. Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~
~~G. Radon-222 as seeds for interstitial treatment of cancer; and~~
~~H. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions.~~
~~I. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.~~

401. Surveys After Source Implant And Removal.

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

B. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee shall retain a record of the surveys required by G 401.A and G.401 B in accordance with G 2401.

402. Brachytherapy Sources Accountability.

A. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area

C. A licensee shall maintain a record of the brachytherapy source accountability in accordance with G 2402.

4031. Safety Instruction.

In addition to the requirements of Part D.

A. The licensee shall provide ~~oral and written~~ radiation safety instruction initially and at least annually to all personnel caring for a patients or human research subjects who are receiving brachytherapy ~~implant therapy~~ And cannot be released under G 30. ~~Refresher training shall be provided at intervals not to exceed 1 year.~~ To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include

~~B. To satisfy G 401 A, the instruction shall describe:~~

~~(1.)~~ Size and appearance of the brachytherapy sources;

~~(2.)~~ Safe handling and shielding instructions; ~~in case of a dislodged source;~~

~~(3.)~~ ~~Procedures for~~ pPatient and human research subject control,

~~(3)~~4 ~~Procedures for v~~Visitor control; including both~~:~~ ~~and~~

a. Routine visitation of hospitalized individuals in accordance with Part D 14 A 1; and

b Visitation authorized in accordance with Part D.14 C; and

~~(4)~~5. ~~Procedures for n~~Notification of the Radiation Safety Officer, or his or her designee, and an ~~or~~ authorized user if the patient or human research subject ~~dies or~~ has a medical emergency or dies.

B~~C~~. A licensee shall retain ~~maintain~~ a record of individuals receiving instruction in accordance with G 2301 ~~required by G.401 A, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 2 years.~~

4040~~2~~. Safety Precautions.

A. For each patient or human research subject who is receiving brachytherapy ~~implant therapy~~and cannot be release under G 30, a licensee shall:

~~(1.)~~ Not quarter ~~place~~ the patient or human research subject in the same room as an individual ~~with a patient~~ who is not receiving brachytherapy, ~~radiation therapy unless the licensee can demonstrate compliance with the requirement of D 14. of these regulations at a distance of 1 meter from the implant;~~

~~(2.)~~ Visibly ~~P~~post the patient's or human research subject's room ~~door~~ with a "~~Caution~~ Radioactive Materials" sign; and

3. N~~n~~ote on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

~~(3) Authorize visits by individuals under 18 years of age only on a case by case basis with the approval of the authorized user after consultation with the Radiation Safety Officer,~~

~~(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with D.14 of these regulations and retain for 2 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems ((Sv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and~~

~~(5) Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.~~

B A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

1. Dislodged from the patient or human research subject; and

2. Lodged within the patient or human research subject following removal of the source applicators.

CB. A licensee shall notify the Radiation Safety Officer or his or her designee, and an authorized user as soon as possible ~~immediately~~ if the patient or human research subject ~~dies or~~ has a medical emergency or dies.

~~**403. Brachytherapy Sources Inventory.**~~

~~A. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.~~

~~B. A licensee shall make a record of brachytherapy source utilization which includes:~~

~~(1) The names of the individuals permitted to handle the sources;~~

~~(2) The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and~~

~~(3) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.~~

~~C. Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.~~

~~D. A licensee shall maintain the records required in G.403.B. and C. for 2 years.~~

~~**404. Release of Patients Treated With Temporary Implants.**~~

~~A. Immediately after removing the last temporary implant source from a patient, the licensee shall ask a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.~~

~~B. A licensee shall maintain a record of patient surveys, which demonstrate compliance with G.404.A. for 2 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.~~

~~**405. Possession of Survey Instruments.** A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 (Sv) per hour to 50 millirems (500 (Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 (Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with G.18.~~

405. Calibration Measurements Of Brachytherapy Sources.

A. Before the first medical use of a brachytherapy source on or after *[insert date 6 months from publication of the Final Rule]*, a licensee shall have:

1. Determined the source output or activity using a dosimetry system that meets the requirements of G 605.A·

2. Determined source positioning accuracy within applicators; and

3. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G 405 A.1 and G 405 A 2

B A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with G 405 A

C. A licensee shall mathematically correct the outputs or activities determined in G 405 A for physical decay at intervals consistent with 1 percent physical decay

D. A licensee shall retain a record of each calibration in accordance with G 2405

406. Decay Of Strontium-90 Sources For Ophthalmic Treatments.

A Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments The decay must be based on the activity determined under G 405

B A licensee shall retain a record of the activity of each strontium-90 source in accordance with G 2406

407. Therapy-Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies At a minimum, the acceptance testing must include, as applicable, verification of

A The source-specific input parameters required by the dose calculation algorithm;

B The accuracy of dose, dwell time, and treatment time calculations at representative points,

C. The accuracy of isodose plots and graphic displays; and

D. The accuracy of the software used to determine sealed source positions from radiographic images

490. Training For Use Of Manual Brachytherapy Sources.

Except as provided in G.21, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G 400 to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G 490 B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Radiology in radiology, therapeutic radiology or radiation oncology, or,

2. American Osteopathic Board of Radiology in radiation oncology; or,

3. British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" in radiology with a specialization in radiotherapy; or

4. Canadian Royal College of Physicians and Surgeons in therapeutic radiology, or

B. 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

a. 200 hours of classroom and laboratory training in the following areas:

(2) Radiation physics and instrumentation;

(3) Radiation protection;

(4) Mathematics pertaining to the use and measurement of radioactivity; and

(5) Radiation biology; and

b 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.490 or equivalent NRC, Agreement State, or Licensing State requirements at a medical institution, involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Checking survey meters for proper operation;

(3) Preparing, implanting, and removing brachytherapy sources;

(4) Maintaining running inventories of material on hand,

(5) Using administrative controls to prevent a medical event involving the use of radioactive material;

(6) Using emergency procedures to control radioactive material; and

2. Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G 490 or equivalent NRC, Agreement State, or Licensing State, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490.B 1.b.; and

3. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G.490 or equivalent NRC, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G 490 B 1. and G 490 B.2. and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G 400.

491. Training For Ophthalmic Use Of Strontium-90.

Except as provided in G 21, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

A. Is an authorized user under G 490 or equivalent NRC, Agreement State, or Licensing State requirements; or

B 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d Radiation biology, and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals This supervised clinical training must involve:

a. Examination of each individual to be treated;

b. Calculation of the dose to be administered;

c. Administration of the dose; and

d. Follow up and review of each individual's case history; and

3. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in G 490, G.491, or equivalent NRC, Agreement State, or Licensing State requirements, that the individual has satisfactorily completed the requirements in G 491 A and G 491 B and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use

SUBPART G - Sealed Sources for Diagnosis

500. Use of Sealed Sources for Diagnosis.

A licensee shall use only ~~the following~~ sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.~~in accordance with the manufacturer's radiation safety and handling instructions:~~

~~A. Iodine-125 as a sealed source in a device for bone mineral analysis;~~
~~B. Americium-241 as a sealed source in a device for bone mineral analysis;~~
~~C. Gadolinium-153 as a sealed source in a device for bone mineral analysis; and~~
~~D. Iodine-125 as a sealed source in a portable device for imaging.~~

~~**501. Availability of Survey Instrument.** A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 (Sv) per hour to 50 millirems (500 (Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 (Sv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with G.18.~~

G.590. Training For Use Of Sealed Sources For Diagnosis.

Except as provided in G.21, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

A. Is certified by a specialty board whose certification process includes all of the requirements in G.590 B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Radiology in radiology, diagnostic radiology, therapeutic radiology or radiation oncology; or,

2. American Board of Nuclear Medicine in nuclear medicine; or,

3. American Osteopathic Board of Radiology in diagnostic radiology or radiology; or

4. Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

B. Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Training in the use of the device for the uses requested.

SUBPART H – PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS ~~Teletherapy~~

600. Use Of A Sealed Source In A Remote Afterloader Unit, Teletherapy Unit, Or Gammastereotactic Radiosurgery Unit.~~,~~

A licensee shall use ~~cobalt-60 or cesium-137 as a~~ sealed sources in photon emitting remote afterloader units. ~~in~~ a teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses ~~for medical use in accordance with the manufacturer's radiation safety and operating instructions~~

A As approved in the Sealed Source and Device Registry, or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration (FDA) provided the requirements of G 17 are met

601 Surveys Of Patients And Human Research Subjects Treated With A Remote Afterloader Unit.

A Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

B. A licensee shall retain a record of these surveys in accordance with G 2401.

602~~1~~. Installation, Maintenance, Adjustment and Repair ~~Restrictions.~~

A Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~to perform teletherapy unit maintenance and repair~~ shall install, maintain, adjust, or repair ~~relocate, or remove~~ a remote afterloader unit, ~~teletherapy sealed source or a~~ teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s) ~~that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.~~

B. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, NRC, Agreement State, or Licensing State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, U S. Nuclear Regulatory Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

D. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G 2602.

~~**602. Amendments.** In addition to the requirements specified in G 4, a licensee shall apply for and receive a license amendment before:~~

~~A. Making any change in the treatment room shielding;~~

~~B. Making any change in the location of the teletherapy unit within the treatment room;~~

~~C. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;~~

~~D. Relocating the teletherapy unit; or~~

~~E. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.~~

~~**603. Safety Instruction.**~~

~~A. A licensee shall post written instructions at the teletherapy unit console. These instructions shall inform the operator of:~~

~~(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;~~

~~(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and~~

~~(3) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.~~

~~B. A licensee shall provide instruction in the topics identified in G.603.A. to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed 1 year.~~

~~C. A licensee shall maintain a record of individuals receiving instruction required by G.603.B., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 2 years.~~

603. Safety Procedures And Instructions For Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units.

A. A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

B. A copy of the procedures required by G.603.A.4 must be physically located at the unit console.

C. A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by G.603.A.4; and

2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

D. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in G.603.A.4; and

2. The operating procedures for the unit.

E. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

F. A licensee shall retain a record of individuals receiving instruction required by G.603.D, in accordance with G.2301.

G. A licensee shall retain a copy of the procedures required by G.603.A.4 and G.603.D.2 in accordance with G.2603.

604. Safety Precautions For Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units ~~Doors, Interlocks, and Warning Systems.~~

A. A licensee shall control access to the treatment ~~teletherapy~~ room by a door at each entrance

B A licensee shall equip each entrance to the treatment ~~teletherapy~~ room with an electrical interlock system that will ~~shall:~~

(1.) Prevent the operator from initiating the treatment cycle ~~turning the primary beam of radiation "on"~~ unless each treatment room entrance door is closed;

(2.) Cause the source(s) to be shielded when an entrance door is opened, and ~~Turn the beam of radiation "off" immediately when an entrance door is opened, and~~

(3.) Prevent the source(s) from being exposed ~~primary beam of radiation from being turned "on"~~ following an interlock interruption until all treatment room entrance doors are closed and the source(s) ~~beam~~ on-off control is reset at the console

C ~~C~~ A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels ~~equip each entrance to the teletherapy room with a beam condition indicator light.~~

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F In addition to the requirements specified in G.604 A through G.604 E, a licensee shall

1 For medium dose-rate and pulsed dose-rate remote afterloader units, require:

a. An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit, and

b. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit

2. For high dose-rate remote afterloader units, require

a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

b. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4 Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies

G A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

1. Remaining in the unshielded position;

2 Lodged within the patient following completion of the treatment.

~~605. Possession of Survey Instrument. A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 (Sv) per hour to 50 millirems (500 (Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 (Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with G.18.~~

~~606. Radiation Monitoring Device.~~

~~A. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.~~

~~B Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.~~

~~C. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.~~

~~D. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.~~

~~E. A licensee shall maintain a record of the check required by G 606.D for 2 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.~~

~~F. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in G.606 E.~~

~~G. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.~~

~~607. Viewing System. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.~~

6058. Dosimetry Equipment.

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a~~A~~ licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1.) The system must ~~shall~~ have been calibrated by the National Institute of Standards and Technology (NIST ~~formerly the National Bureau of Standards~~) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must ~~shall~~ have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2.) The system must ~~shall~~ have been calibrated within the previous 4 years.; Eighteen to thirty ~~18 to 30~~ months after that calibration, the system must ~~shall~~ have been intercompared ~~at an intercomparison meeting~~ with another dosimetry system that was calibrated within the past 24 months by ~~the~~ NIST ~~National Bureau of Standards~~ or by a calibration laboratory accredited by the AAPM ~~American Association of Physicists in Medicine~~. ~~The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~ The results of the intercomparison ~~meeting~~ must ~~have~~ indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may ~~shall~~ not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources ~~cobalt-60 teletherapy~~ for therapeutic units, the licensee shall use a comparable ~~teletherapy~~ unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility. ~~a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.~~

B. The licensee shall have ~~available for use~~ a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy ~~meet~~ this requirement, the system may be compared with a system

that has been calibrated in accordance with G 605.A ~~G 608 A~~ This comparison must ~~shall~~ have been performed within the previous year and after each servicing that may have affected system calibration The spot-check system shall be the same system used to meet the requirement in G 605 A ~~G 608 A~~

C. The licensee shall maintain a record of each calibration, intercomparison, and comparison in accordance with G.2605. ~~for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G 608.A and B , the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~

6069. Full Calibration Measurements On Teletherapy Units.

A. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1.) Before the first medical use of the unit; and

(2.) Before medical use under the following conditions:

(a.) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b.) Following replacement of the source or following reinstallation of the teletherapy unit in a new location, ~~and~~

(c.) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

(3.) At intervals not exceeding 1 year.

B. To satisfy the requirement of G 606 A ~~G 609 A.~~, full calibration measurements must ~~shall~~ include determination of:

(1.) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2.) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3.) The uniformity of the radiation field and its dependence on the orientation of the useful beam,

(4.) Timer accuracy and linearity over the range of use;

(5.) "On-off" error; and

(6.) The accuracy of all distance measuring and localization devices in medical use.

C. A licensee shall use the dosimetry system described in G.605 A ~~G.608~~ to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.605.B.1 ~~G.609 B (1)~~ may ~~then~~ be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by G 606 A ~~G.609.A.~~ in accordance with published protocols accepted by nationally recognized bodies. ~~either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp 741-771, and Vol. 11, No. 2, 1984, p.213.~~

E. A licensee shall mathematically correct ~~mathematically~~ the outputs determined in G.606.B.1 ~~G.609.B.(1)~~ for physical decay for intervals not exceeding 1 month for cobalt-60, ~~and intervals not exceeding~~ 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides..

F. Full calibration measurements required by G.606.A ~~G.609.A.~~ and pPhysical decay corrections required by G 606.E ~~G.609.E.~~ must ~~shall~~ be performed by a the authorized medical ~~teletherapy~~ physicist.

G. A licensee shall retain ~~maintain~~ a record of each calibration in accordance with G.2606. ~~for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.~~

607. Full Calibration Measurements On Remote Afterloader Units.

A. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding 1 year for low dose-rate remote afterloader units

B To satisfy the requirement of G.607.A, full calibration measurements must include, as applicable, determination of

1. The output within +/- 5 percent;

2. Source positioning accuracy to within +/- 1 millimeter;

3. Source retraction with backup battery upon power failure;

4. Length of the source transfer tubes;

5 Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

C. A licensee shall use the dosimetry system described in G.605.A to measure the output

D. A licensee shall make full calibration measurements required by G.607.A in accordance with published protocols accepted by nationally recognized bodies.

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.607.B, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

F. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.607.A through G.607 E.

G A licensee shall mathematically correct the outputs determined in G 607 B 1 for physical decay at intervals consistent with 1 percent physical decay.

H. Full calibration measurements required by G 607 A and physical decay corrections required by G 607.G must be performed by the authorized medical physicist.

I A licensee shall retain a record of each calibration in accordance with G.2606.

608. Full Calibration Measurements On Gamma Stereotactic Radiosurgery Units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1 Before the first medical use of the unit;

2 Before medical use under the following conditions:

a Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location, and

c Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly, and

3 At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

B. To satisfy the requirement of G 608 A, full calibration measurements must include determination of:

1 The output within +/-3 percent;

2. Relative helmet factors,

3. Isocenter coincidence,

4. Timer accuracy and linearity over the range of use;

5. On-off error,

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitches;

9. Emergency timing circuits, and

10. Stereotactic frames and localizing devices (trunnions).

C. A licensee shall use the dosimetry system described in G 605.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.608 B 1 may be made using a dosimetry system that indicates relative dose rates

D. A licensee shall make full calibration measurements required by G.608.A in accordance with published protocols accepted by nationally recognized bodies.

E A licensee shall mathematically correct the outputs determined in G 608.B 1 at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

F Full calibration measurements required by G.608 A and physical decay corrections required by G.608.E must be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration in accordance with G.2606.

6094~~10~~. Periodic Spot Checks For Teletherapy Units..

A. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of ~~--at intervals not to exceed 1 month.~~

~~B To satisfy the requirement of G.610.A , spot checks shall include determination of:~~

(1.) Timer accuracy, ~~constancy~~ and timer linearity over the range of use;

(2.) "On-off" error;

(3.) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4.) The accuracy of all distance measuring and localization devices used for medical use;

(5.) The output for one typical set of operating conditions measured with the dosimetry system described in G 605.A; and

(6.) The difference between the measurement made in G.609.B.5 ~~G.610.B.(5)~~ and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

~~C. A licensee shall use the dosimetry system described in G.608 to make the spot check required in G.610.B.(5).~~

B~~D~~. A licensee shall perform measurements ~~spot checks~~ required by G 609.A ~~G.610.A~~. in accordance with written procedures established by the authorized medical ~~teletherapy~~ physicist. That individual need ~~does~~ not ~~need to~~ actually perform the ~~output~~ spot-check measurements.

C~~E~~. A licensee shall have the authorized medical ~~teletherapy~~ physicist review the results of each ~~output~~ spot check within 15 days. The authorized medical ~~teletherapy~~ physicist shall ~~promptly~~ notify the licensee as soon as possible in writing of the results of each ~~output~~ spot check. ~~The licensee shall keep a copy of each written notification for 2 years.~~

D~~F~~. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of ~~-- at intervals not to exceed 1 month.~~

~~G To satisfy the requirement of G.610.F , safety spot checks shall assure proper operation of:~~

(1.) Electrical interlocks at each teletherapy room entrance,

(2.) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism);

(3.) Source exposure ~~Beam condition~~ indicator lights on the teletherapy unit, on the control console, and in the facility;

(4.) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room, and

(6.) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off"

E~~H~~ If the results of the checks required in G 609 D indicate the malfunction of any system, a~~A~~ licensee shall lock the control console in the "off" position ~~if any door interlock malfunctions. No licensee shall~~ not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. ~~until the interlock system is repaired unless specifically authorized by the Agency.~~

~~I. A licensee shall promptly repair any system identified in G 610 G that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.~~

F~~J~~. A licensee shall retain ~~maintain~~ a record of each spot- check required by G 609.A ~~G 610.A~~. and D.~~F~~, and a copy of the procedures required by G 609 B, in accordance with G 2609. ~~for 2 years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.~~

610. Periodic Spot-Checks For Remote Afterloader Units.

A A licensee authorized to use a remote afterloader unit for medical use shall perform spot- checks of each remote afterloader facility and on each unit:

1 Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

2 Before each patient treatment with a low dose-rate remote afterloader unit, and

3. After each source installation.

B. A licensee shall perform the measurements required by G.610 A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D To satisfy the requirements of G 610 A, spot-checks must, at a minimum, assure proper operation of

1. Electrical interlocks at each remote afterloader unit room entrance,

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

4 Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

E. If the results of the checks required in G.610.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system

F. A licensee shall retain a record of each check required by G.610 D and a copy of the procedures required by G.610.B in accordance with G.2610.

611. Periodic Spot-Checks For Gamma Stereotactic Radiosurgery Units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

1. Monthly;

2 Before the first use of the unit on a given day; and

3 After each source installation.

B. A licensee shall—

1. Perform the measurements required by G.611.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

2. Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

C. To satisfy the requirements G.611.A.1, spot-checks must, at a minimum –

1. Assure proper operation of:

a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

b. Helmet microswitches;

c. Emergency timing circuits; and

d. Stereotactic frames and localizing devices (trunnions).

2. Determine:

a. The output for one typical set of operating conditions measured with the dosimetry system described in G 605 A;

b. The difference between the measurement made in G.611.C.2 a and the anticipated output, expressed as a percentage of the anticipated output (i e , the value obtained at last full calibration corrected mathematically for physical decay);

c Source output against computer calculation,

d. Timer accuracy and linearity over the range of use;

e. On-off error, and

f Trunnion centricity.

D. To satisfy the requirements of G 611 A 2 and G 611 3, spot-checks must assure proper operation of –

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility,

3. Viewing and intercom systems;

4. Timer termination;

5 Radiation monitors used to indicate room exposures, and

6 Emergency off buttons

E. A licensee shall arrange for the repair of any system identified in G 611 C that is not operating properly as soon as possible.

F If the results of the checks required in G 611 D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee shall retain a record of each check required by G 611 C and G 611 D and a copy of the procedures required by G.611 B in accordance with G.2611.

612. Additional Technical Requirements For Mobile Remote Afterloader Units.

A. A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent, and

2. Account for all sources before departure from a client's address of use.

B In addition to the periodic spot-checks required by G 610, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use At a minimum, checks must be made to verify the operation of –

1 Electrical interlocks on treatment area access points,

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3 Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in G.612.B., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D If the results of the checks required in G.612.B indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee shall retain a record of each check required by G.612.B in accordance with G.2612

6131. Radiation Surveys ~~For Teletherapy Facilities.~~

A In addition to the survey requirement in Part D.17, a person licensed under Part G shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee shall make the survey required by G 613.A at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

C. A licensee shall retain a record of the radiation surveys required by G.613.A in accordance with G.2613.

~~A. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by G.602, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with G.18 to verify that:~~

~~(1) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 (Sv) per hour and 2 millirems (20 (Sv) per hour, respectively; and~~

~~(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:~~

~~(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in D.6. of these regulations; and~~

~~(b) Radiation levels in unrestricted areas do not exceed the limits specified in D.14. of these regulations.~~

~~B. If the results of the surveys required in G.611.A. indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:~~

~~(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or~~

~~(2) Until the licensee has received a specific exemption from the Agency.~~

~~C. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer~~

~~612. Safety Spot Checks for Teletherapy Facilities~~

~~A. A licensee shall promptly spot check all systems listed in G.610.G. for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by G.602.~~

~~B. If the results of the spot checks required in G.612.A. indicate the malfunction of any system specified in G.610, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.~~

~~C. A licensee shall maintain a record of the facility checks following installation of a source for 2 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.~~

~~**613. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.** If the survey required by G.611. indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by D.14. of these regulations, before beginning the treatment program the licensee shall:~~

~~A. Either equip the unit with stops or add additional radiation shielding to ensure compliance with D.14. of these regulations;~~

~~B. Perform the survey required by G.611 again; and~~

~~C. Include in the report required by G.614 the results of the initial survey, a description of the modification made to comply with G.613.A., and the results of the second survey; or~~

~~D. Request and receive a license amendment under D.14.C. of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by D.14.A. of these regulations.~~

~~**614. Reports of Teletherapy Surveys, Checks, Tests, and Measurements.** A licensee shall furnish a copy of the records required in G.611, G.612, G.613 and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source and determined during the full calibration required in G.609 to the Agency within 30 days following completion of the action that initiated the record requirement.~~

6145. Five Year Inspection For Teletherapy And Gamma Stereotactic Radiosurgery Units.

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during ~~teletherapy~~ source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may ~~shall~~ only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State., ~~or the U.S. Nuclear Regulatory Commission.~~

C. A licensee shall keep ~~maintain~~ a record of the inspection and servicing in accordance with G.2614. ~~for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.~~

615. Therapy-Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

C. The accuracy of isodose plots and graphic displays,

D. The accuracy of the software used to determine sealed source positions from radiographic images; and

E. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

690. Training For Use Of Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units.

Except as provided in G.21, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who:

A Is certified by a medical specialty board whose certification process includes all of the requirements in G.690.B and whose certification has been recognized by the Agency, NRC, Agreement State, or Licensing State;

1. American Board of Radiology in radiology, therapeutic radiology or radiation oncology; or

2. American Osteopathic Board of Radiology in radiation oncology; or,

3. British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" in radiology with a specialization in radiotherapy; or

4. Canadian Royal College of Physicians and Surgeons in therapeutic radiology; or

B. 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes –

a. 200 hours of classroom and laboratory training in the following areas –

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

b 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.690 or equivalent NRC, Agreement State, or Licensing State requirements at a medical institution, involving:

(1) Reviewing full calibration measurements and periodic spot-checks;

(2) Preparing treatment plans and calculating treatment doses and times;

(3) Using administrative controls to prevent a medical event involving the use of radioactive material;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(5) Checking and using survey meters; and

(6) Selecting the proper dose and how it is to be administered; and

2 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.690 or equivalent NRC, Agreement State, or Licensing State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association This experience may be obtained concurrently with the supervised work experience required byG 690 B.1.a; and

3. Has obtained written certification that the individual has satisfactorily completed the requirements in G.690 B.1 and G.609 B 2 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in G.690 or equivalent NRC, Agreement State, or Licensing State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

SUBPART I - CYCLOTRON/PET FACILITIES

700. Licensing and Registration of Cyclotron/PET Facilities

A. The cyclotron/PET facility components shall be licensed pursuant to the following criteria:

1. The accelerator shall be registered pursuant to Part I.

2. The processing, manufacturing, and distribution of radioactive material shall be licensed pursuant to Part C.

3. The nuclear pharmacy shall be licensed pursuant to Part C.

4. The PET medical use shall be licensed pursuant to Part C, but may be approved under an existing specific license for radioactive material for human use (nuclear medicine) via the amendment process.

B The licensee or registrant shall receive applicable agency authorization prior to the production of any accelerator-produced radioactive material or any change in accelerator configuration, shielding, location, room shielding or configuration, nuclide production method, ventilation systems, rabbit or other delivery systems, operating or emergency procedures, radiation safety personnel, authorized users or operators, or other applicable provisions authorized pursuant to these rules.

701. Supervision of Cyclotron/PET Facilities

A Management shall ensure that there is a qualified Radiation Safety Officer (RSO) who shall oversee the radiation safety aspects of the cyclotron/PET facility and be responsible for radiation safety of the cyclotron accelerator and the nuclear pharmacy.

1. In the case of a nuclear medicine service associated with the cyclotron/PET facility, there shall be a cooperative consortium of management and radiation safety personnel that acts as directors for the both the facility and the clinic;

2. Management, whether singular or in consortium, shall write a statement of authority and responsibility for all staff handling or controlling the production and use of cyclotron produced radioactive material and PET isotopes.

B. The RSO shall be assisted by personnel specifically trained and designated for the area of concern, whether cyclotron accelerator operation or radiopharmaceutical production.

~~C. There shall be a Radiation Safety Committee (RSC) for a cyclotron/PET facility. The RSC can be a sub-committee of an institutional RSC or a conjoint committee of individual licenses where several licensees are cooperating in the Cyclotron/PET facility.~~

702. Other Applicable Requirements

A. The licensee shall ensure that any radiopharmaceutical for which an Investigational New Drug (IND) status does not exist, or which shall be used for research purposes in humans, is reviewed by an Institutional Review Board (IRB) or Human Subjects Review Board or Committee. The licensee shall establish procedures, reviews, quality assurance, and emergency procedures for all procedures reviewed by the IRB. The IRB, ~~the Radiation Safety Committee or subcommittee,~~ and the Radiation Safety Officer shall review and approve any and all PET procedures, unless otherwise authorized in a radioactive materials license pursuant to Part C.7.

B. Transfers of radioisotopes shall be in accordance with requirements in Part C.21.

C. Cyclotron/PET facility radiation protection programs, occupational dose limits, radiation dose limits for the public, surveys and monitoring, restricted area control, storage of radioactive materials, internal exposure control, precautionary procedures, waste disposal, records, and reports shall meet all applicable requirements of Part D ~~of these rules~~

703. Cyclotron/PET Facility Accelerator Requirements.

Accelerators shall meet all requirements of Part I in shall also meet the following additional requirements:

A Shielded-room accelerators shall be equipped with interlocks and personnel control; self-shielded accelerators shall be shielded such that personnel access is prevented during operation.

B Target maintenance and repair, contamination control, and emergency actions shall be conducted pursuant to Part D ~~of these rules~~

C. There shall be an Understanding of Transfer (UOT) when isotopes are transferred from one licensee or entity to another for processing, specifying at what point control is transferred to personnel handling radiochemical production or nuclear pharmacy operation.

D Radiation surveys shall be made prior to any accelerator operation or isotope production with a radiation survey instrument calibrated in accordance with requirements in G.23 ~~Part G 303~~. Periodic surveys shall be done throughout times of operation to ensure that radiation levels meet all applicable requirements in Part D. ~~(Standards for Protection Against Radiation)~~

E. Ventilation controls shall be implemented to ensure compliance with all applicable local, state, and federal requirements. Controls shall include monitoring of stacks and computer modeling of air emissions to confirm compliance with standards.

F. Real-time (integrating) monitors shall be used to confirm requirements in Parts D.6 , D.12 , D.13,, and D.14

~~G. Contamination wipes for radioactive material shall be made pursuant to requirements in Part G 26 ;~~

G.~~H~~ Dosimetry must address both gamma and beta doses in all areas of the facility. Licensees and registrants must monitor extremities to ensure compliance with Part D.~~6~~. Bioassays, as defined ~~in Part~~in Part A 2.(19~~16~~), are not required, but there must be evaluation of internal exposures, pursuant to Part D 9 , based on calculated releases and monitoring.

704. Safety Considerations for Cyclotron/PET Facilities

A. Area monitors must be visible and audible to accelerator operators Monitors must be checked for proper operation daily.

B. Wasted targets shall be treated as radioactive waste and must be properly dismantled, shielded, stored, and disposed.

C. Accelerator shielding design and safety shall meet requirements of Part I.7.

D. Shielding around guide-bends, targets, hot-cells, purification manifolds, etc. shall ensure that limits in Parts D 14. and D.15 have been met in all areas of beam and nuclide production.

E. Security provisions for unauthorized access, janitorial services, maintenance, visitors, tours, and personnel-in-training shall conform to requirements in Parts D.14., D 25, and D 26

705. Cyclotron/PET Facility Nuclear Pharmacy and Radiochemical Production

A. All preparations used in humans shall meet the State of Maine Board of Pharmacy standards, as well as applicable federal Food and Drug Administration (FDA) requirements.

~~(1)~~1 All research products to be used in humans shall be reviewed and approved by the licensee's or consortium Institutional Review Board (IRB) or Radioactive Drug Research Committee (RDRC)

~~(2)~~2 No research radiopharmaceutical shall be used in a human being until its pyrogenicity and purity have been shown to meet applicable standards.

B. Cyclotron facility staff shall work directly under the supervision of a cyclotron/PET Facility authorized user as per ~~Part~~ G.990.

C. There shall be no transfers between or among licensees unless there is a signed Memorandum or Understanding of Transfer. Such memorandum shall preclude any transfers from one licensee entity to another if there is incomplete information, purity questions, or non-approval from the IRB or RDRC.

D. There shall be a detailed description of the shielding and operation of the "black box" (hot cell).

E. There shall be operating and emergency, training, and survey procedures for ease of movement of the product within the pharmacy production area. Emergency procedures must address potential high dose rate emergencies such as stuck rabbit (transport container), pneumatic tube contamination, manifold leak or spill, hot cell emergency, or other incident.

F. Equipment and procedures shall include:

~~(1)~~1. —Air processing system (e.g. hood with stack monitoring) with continuous effluent monitoring to assure compliance with air emission standards;

~~(2)~~2 Remote handling equipment for very high dose rates (all handling must be done remotely),

~~(3)~~3. Dose calibration, system validation, and calibration standards, for all individual doses;

~~(4)~~4. Ba-133 shall not be used as a calibration source;

~~(5)~~5 Dose calibrator linearity check using a positron emitter (beta shield must be evaluated to prevent interference with annihilation measurement);

~~(6)~~6. –Product delivery system design, shielding, carrier, and emergency procedures;

~~(7)~~7 –Leak tests (hermeticity) of delivery container;

~~(8)~~8 –Labeling requirements, transportation manifests, and packaging for outside deliveries;

~~(9)~~9. –Transportation requirements pursuant to Part L of these rules;

~~(10)~~10 Inventory control, "cradle to grave" tracking, and communication with PET clinic;

~~(11)~~ 11. Waste disposal procedures.

706. Rubidium-82 Generator. Rubidium-82 generators require quality assurance procedures for equipment, patient injection, waiting area, imaging, and post-imaging care. There also must be a procedure for spills, and a handling procedure for liquid quality assurance sources for early model PET cameras. Dose calibration procedures are the same as in ~~Part~~ G. 705.F.

790. Training for Cyclotron/PET Facility Authorized Users

The licensee shall require the authorized user who will operate the cyclotron or process cyclotron products without direct supervision shall be an Authorized Nuclear Pharmacist as per G.20 or have equivalent professional training and experience as deemed appropriate by the Agency, as well as specific training and experience relevant to work in a cyclotron/PET facility This should include:

A. Additional training in cyclotron physics and radiation safety, targetry, radiochemistry, use of automated and semi-automated chemical synthesis devices, quality control, airborne emissions verification and evaluation, and the regulatory standards and

B. Cyclotron manufacturer's training

791. Training for Cyclotron/Pet Facility Staff.

The licensee shall require that staff who will participate in operation of the cyclotron or processing of cyclotron products under the supervision of authorized users have appropriate training and experience. This should include:

A. Certified in nuclear medicine technology by the State of Maine Radiologic Technology Board of Examiners, or

B. Certified in Pharmacy Technology by the State of Maine Board of Pharmacy or

C. Have equivalent professional training and experience as deemed appropriate by the Agency and

D. Additional instruction in radiation safety precautions and procedures, regulatory and license requirements, operating and emergency procedures, cyclotron operation, use of related equipment and of survey and monitoring equipment as appropriate to their assigned tasks

SUBPART J - TRAINING AND EXPERIENCE REQUIREMENTS

900 Radiation Safety Officer.
Except as provided in G.901, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G 7 shall::
A. Be certified by the:
(1) American Board of Health Physics in Comprehensive Health Physics;
(2) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;
(3) American Board of Nuclear Medicine;
(4) American Board of Science in Nuclear Medicine, or
(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or
B. Have had 200 hours of classroom and laboratory training as follows::
(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology;
(5) Radiopharmaceutical chemistry; and
(6) 1 year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or
C. Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

901. Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on *August 27, 1987* who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of G 900.

910. Training for Uptake, Dilution, or Excretion Studies. Except as provided in G.970 and G 971, the licensee shall require the authorized user of a radiopharmaceutical listed in G 100 to be a physician who:
A. Is certified in:
(1) Nuclear medicine by the American Board of Nuclear Medicine; G.910.A(2)
(2) Diagnostic radiology by the American Board of Radiology; or
(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or
(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine.
B. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.
(1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:
(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Radiation biology; and
(e) Radiopharmaceutical chemistry.
(2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:
(a) Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
(c) Administering dosages to patients and using syringe radiation shields;
(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and

C. Patient follow-up; or has successfully completed a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in G 910 B.

920. Training for Imaging and Localization Studies. Except as provided in G 970 or G.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in G 200 to be a physician who:

A. Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine, G 920 A(2)

(2) Diagnostic radiology by the American Board of Radiology, or

(3) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or

(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine.

B. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.a

(1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiopharmaceutical chemistry; and

(e) Radiation biology

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(c) Calculating and safely preparing patient dosages;

(d) Using administrative controls to prevent the misadministration of radioactive material;

(e) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures, and

(f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals

(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;(c) Administering dosages to patients and using syringe radiation shields,

(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(e) Patient follow-up; or

C. Has successfully completed a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in G 920 B..

930. Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in G 970, the licensee shall require the authorized user of a radiopharmaceutical listed in G 300 for therapy to be a physician who:

A. Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology or therapeutic radiology, or

B. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience:

(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity, and

(d) Radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

(b) Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

(c) Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and G.930 B(2)

(d) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals

940. **Training for Therapeutic Use of Brachytherapy Sources.** Except as provided in G.970, the licensee shall require the authorized user using a brachytherapy source specified in G.400 for therapy to be a physician who:

A. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

B. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of 3 years of supervised clinical experience:

(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing sealed sources;

(d) Using administrative controls to prevent the misadministration of radioactive material, and

(e) Using emergency procedures to control radioactive material.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(a) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(b) Selecting the proper brachytherapy sources, dose, and method of administration;

(c) Calculating the dose; and

(d) Post-administration follow-up and review of case histories in collaboration with the authorized user.

941. **Training for Ophthalmic Use of Strontium-90.** Except as provided in G.970, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who::

A. Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

B. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and

(d) Follow-up and review of each individual's case history.

950. Training for Use of Sealed Sources for Diagnosis. Except as provided in G 970, the licensee shall require the authorized user using a sealed source in a device specified in G 500 to be a physician, dentist, or podiatrist who:

A. Is certified in:

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology, or

B. Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation,

(2) Radiation biology; and

(3) Radiation protection and training in the use of the device for the purposes authorized by the license.

Training For Teletherapy. Except as provided in G 970, the licensee shall require the authorized user of a sealed source specified in G 600 in a teletherapy unit to be a physician who:

A. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology,

(2) Radiation oncology by the American Osteopathic Board of Radiology,

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology", or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons, or

B. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.:

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity, and

(d) Radiation biology.

(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include.

(a) Review of the full calibration measurements and periodic spot checks;

(b) Preparing treatment plans and calculating treatment times;

(c) Using administrative controls to prevent misadministrations;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console, and

(e) Checking and using survey meters.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include

(a) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(b) Selecting the proper dose and how it is to be administered;

(c) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(d) Post-administration follow-up and review of case histories.

Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to:

A. Be certified by the American Board of Radiology in

(1) Therapeutic radiological physics,

(2) Roentgen-ray and gamma-ray physics,

(3) X-ray and radium physics; or

(4) Radiological physics, or

B. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this

requirement, the individual shall have performed the tasks listed in *G.21, G.609, G.610, and G.611* under the supervision of a teletherapy physicist during the year of work experience.

970. Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency, NRC or Agreement State or Licensing State license on *August 27, 1987* who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of G 900 through G 972

971. Physician Training in a Three-Month Program. A physician who, before *July 1, 1984*, began a 3-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of G.910 or G.920.

972. Recentness of Training. The training and experience specified in G.900 through G.991 shall have been obtained within the 5 years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

980. Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who.

A. Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

B. Has completed 700 hours in a structured educational program consisting of both:

(1) Didactic training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection,

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of byproduct material for medical use; and

(e) Radiation biology; and

(2) Supervised experience in a nuclear pharmacy involving the following:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha or beta emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid mistakes in the administration of byproduct material;

(e) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

C. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

981. Training for Experienced Nuclear Pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 980.B.1 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement *(980.C.)* and recentness of training *(972)* to qualify as an authorized nuclear pharmacist.

990. Training for Cyclotron/PET Facility Authorized Users The licensee shall require the authorized user who will operate the cyclotron or process cyclotron products without direct supervision shall be an Authorized Nuclear Pharmacist as per G 980 or have equivalent professional training and experience as deemed appropriate by the Agency, as well as specific training and experience relevant to work in a cyclotron/PET facility. This should include:

A. Additional training in cyclotron physics and radiation safety, targetry, radiochemistry, use of automated and semi automated chemical synthesis devices, quality control, airborne emissions verification and evaluation, and the regulatory standards and

B. Cyclotron manufacturer's training

991. Training for Cyclotron/Pet Facility Staff. The licensee shall require that staff who will participate in operation of the cyclotron or processing of cyclotron products under the supervision of authorized users have appropriate training and experience. This should include:

A. Certified in nuclear medicine technology by the State of Maine Radiologic Technology Board of Examiners, or

B. Certified in Pharmacy Technology by the State of Maine Board of Pharmacy, or

C. Have equivalent professional training and experience as deemed appropriate by the Agency, and

D. Additional instruction in radiation safety precautions and procedures, regulatory and license requirements, operating and emergency procedures, cyclotron operation, use of related equipment and of survey and monitoring equipment as appropriate to their assigned tasks

SUBPART J--OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

1000. Other Medical Uses Of Radioactive Material Or Radiation From Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part G if

A. The applicant or licensee has submitted the information required by G.6 B through G.6 D; and

B. The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

SUBPART K-- RECORDS

2012. Records Of Authority And Responsibilities For Radiation Protection Programs.

A A licensee shall retain a record of actions taken by the licensee's management in accordance with G.12.A for 5 years. The record must include a summary of the actions taken and a signature of licensee management

B. The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.12.E. and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G 12 B. for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

2013. Records Of Radiation Protection Program Changes.

A licensee shall retain a record of each radiation protection program change made in accordance with G.13.A for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

2015. Records Of Written Directives.

A licensee shall retain a copy of each written directive as required by G 15 for 3 years.

2016. Records For Procedures For Administrations Requiring A Written Directive

A licensee shall retain a copy of the procedures required by G.16 A for the duration of the license.

2023. Records Of Calibrations Of Instruments Used To Measure The Activity Of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument calibrations required by G.23 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

2024. Records Of Radiation Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by G.24 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

2025. Records Of Dosages Of Unsealed Radioactive Material For Medical Use.

(a) A licensee shall maintain a record of dosage determinations required by G.25 for 3 years.

(b) The record must contain:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

2027. Records Of Leaks Tests And Inventory Of Sealed Sources And Brachytherapy Sources.

(a) A licensee shall retain records of leak tests required by G.27 B for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.27.G for 3 years The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

2029. Records Of Surveys For Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by G.29 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

2030. Records Of The Release Of Individuals Containing Unsealed Radioactive Material Or Implants Containing Radioactive Material.

A. A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with G.30, if the total effective dose equivalent is calculated by --

1 Using the retained activity rather than the activity administered;

2. Using an occupancy factor less than 0 25 at 1 meter;

3. Using the biological or effective half-life; or

4 Considering the shielding by tissue.

B. A licensee shall retain a record that the instructions required by G 30.B were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0 5 rem)

C. The records required by G.2030 A and G2030 B must be retained for 3 years after the date of release of the individual

2031. Records Of Mobile Nuclear Medicine Services.

A. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by G 31 A 1. Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

B. A licensee shall retain the record of each survey required by G 31.A 4 for 3 years The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

2032. Records Of Decay-In-Storage.

A licensee shall maintain records of the disposal of licensed materials, as required by G 32, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

2201. Records Of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by G 201.B for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per

millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

2301. Records Of Safety Instruction.

A licensee shall maintain a record of safety instructions required by G.301, G.403, and G.603 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction

2401. Records Of Surveys After Source Implant And Removal.

A licensee shall maintain a record of the surveys required by G.401 and G.601 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

2402 Records Of Brachytherapy Source Accountability.

A A licensee shall maintain a record of brachytherapy source accountability required by G.402 for 3 years

B. For temporary implants, the record must include --

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

2. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

C. For permanent implants, the record must include:

1 The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2 The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

2405. Records Of Calibration Measurements Of Brachytherapy Sources.

A. A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.405 for 3 years after the last use of the source.

B The record must include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

3. The source output or activity;

4. The source positioning accuracy within the applicators; and

5. The signature of the authorized medical physicist.

2406. Records Of Decay Of Strontium-90 Sources For Ophthalmic Treatments.

A. A licensee shall maintain a record of the activity of a strontium-90 source required by G.406 for the life of the source.

B The record must include:

1. The date and initial activity of the source as determined under G 405, and

2 For each decay calculation, the date and the source activity as determined under G 406

2602. Records Of Installation, Maintenance, Adjustment, And Repair Of Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G 602 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work

2603. Records Of Safety Procedures

A licensee shall retain a copy of the procedures required by G.603 A 4 and G.603.D.2 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

2605. Records Of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, And Gamma Stereotactic Radiosurgery Units.

A. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G 605 for the duration of the license

(b) For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G 605 A and G.605 B ,

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison

2606. Records Of Teletherapy, Remote Afterloader, And Gamma Stereotactic Radiosurgery Full Calibrations.

A A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by G.606, G.607, and G.608 for 3 years.

B The record must include:

1 The date of the calibration;

2 The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

3 The results and an assessment of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units, and

5. The signature of the authorized medical physicist who performed the full calibration.

2609. Records Of Periodic Spot-Checks For Teletherapy Units.

A. A licensee shall retain a record of each periodic spot-check for teletherapy units required by G 609 for 3 years

B The record must include --

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3 An assessment of timer linearity and constancy;

4 The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G 609 B until the licensee no longer possesses the teletherapy unit.

2610. Records Of Periodic Spot-Checks For Remote Afterloader Units.

A. A licensee shall retain a record of each spot-check for remote afterloader units required by G.610 for 3 years.

B. The record must include, as applicable:

1. The date of the spot-check;

2 The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.610.B until the licensee no longer possesses the remote afterloader unit.

2611. Records Of Periodic Spot-Checks For Gamma Stereotactic Radiosurgery Units.

A. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G 611 for 3 years.

B The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

3. An assessment of timer linearity and accuracy;

4. The calculated on-off error,

5. A determination of trunnion centricity,

6. The difference between the anticipated output and the measured output;

7. An assessment of source output against computer calculations,

8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check

C. A licensee shall retain a copy of the procedures required by G.611 B until the licensee no longer possesses the gamma stereotactic radiosurgery unit

2612. Records Of Additional Technical Requirements For Mobile Remote Afterloader Units.

A A licensee shall retain a record of each check for mobile remote afterloader units required by G 612 for 3 years

B. The record must include

1. The date of the check;

2 The manufacturer's name, model number, and serial number of the remote afterloader unit;

3 Notations accounting for all sources before the licensee departs from a facility;

4 Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy, and

5. The signature of the individual who performed the check.

2613. Records Of Surveys Of Therapeutic Treatment Units.

A A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G 613 for the duration of use of the unit.

B. The record must include:

1 The date of the measurements;

2 The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3 Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test

2614. Records Of 5-Year Inspection For Teletherapy And Gamma Stereotactic Radiosurgery Units.

A. A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G 614 for the duration of use of the unit.

B The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

SUBPART L--REPORTS

3001. Report And Notification Of A Medical Event.

A A licensee shall report any event, except for an event that results from patient intervention in which the administration of radioactive material or radiation from radioactive material results in

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0 05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

a. The total dose delivered differs from the prescribed dose by 20 percent or more,

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range, or

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2 A dose that exceeds 0 05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0 5 Sv (50 rem) shallow dose equivalent to the skin from any of the following·

a An administration of a wrong radioactive drug containing radioactive material;

b An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d An administration of a dose or dosage delivered by the wrong mode of treatment, or

e. A leaking sealed source

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0 5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event

D. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

1 The written report must include·

a The licensee's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual(s) who received the administration;

f. What actions, if any, have been taken or are planned to prevent recurrence, and

g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2 The report may not contain the individual's name or any other information that could lead to identification of the individual

E. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of G.3001 E, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

G. A licensee shall:

1. Annotate a copy of the report provided to the Agency with the:

a. Name of the individual who is the subject of the event; and

b. Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3002. Report And Notification Of A Dose To An Embryo/Fetus Or A Nursing Child.

A A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in G 3002.A or G 3002.B.

D. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in G 3002.A or G.3002.B.

1. The written report must include:

a The licensee's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d Why the event occurred;

e The effect, if any, on the embryo/fetus or the nursing child;

f What actions, if any, have been taken or are planned to prevent recurrence; and

g Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2 The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child

E The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G 3002 A or G 3002 B, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

F. A licensee shall:

1 Annotate a copy of the report provided to the NRC with the·

a Name of the pregnant individual or the nursing child who is the subject of the event and

b. Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3003. Report Of A Leaking Source.

A licensee shall file a report within 5 days if a leak test required by G 27 reveals the presence of 185 Bq (0 005 µCi) or more of removable contamination The report must be filed with the Agency, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test, and the action taken.